



[Signature]
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

in re Application of:

Jones et al.

Serial No.: 10/644,256

Filed: August 20, 2003

For: EFFICIENT PRODUCTION OF IgA
IN RECOMBINANT MAMMALIAN
CELLS

Confirmation No.: 6153

Examiner: To be assigned

Group Art Unit: 1632

Attorney Docket No.: 2578-6077US

CERTIFICATE OF MAILING

I hereby certify that this correspondence along with any attachments referred to or identified as being attached or enclosed is being deposited with the United States Postal Service as First Class Mail on the date of deposit shown below with sufficient postage and in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

August 12, 2005
Date

Betty Vowles
Signature

Betty Vowles
Name (Type/Print)

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO/SB/08 be considered by the Examiner and made of record. Copies of U.S. patents are not being submitted pursuant to M.P.E.P. 609 III A(2). Copies of foreign patent documents and non-patent literature are enclosed pursuant to 37 C.F.R. § 1.98(a)(2) except as noted below.

U.S. Patent Documents

<u>U.S. Patent No.</u>	<u>Publication Date</u>	<u>Patentee</u>
US-4,703,008	10-27-1987	Lin
US- 4,835,260	05-30-1989	Shoemaker
US- 5,047,335	09-10-1991	Paulson et al.
US- 5,441,868	08-15-1995	Lin
US- 5,457,089	10-10-1995	Fibi et al.
US- 5,494,790	02-27-1996	Sasaki et al.
US- 5,767,078	06-16-1998	Johnson et al.
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US- 2003/0092160	05-15-2003	Bout et al.

Foreign Patent Documents

<u>Document No.</u>	<u>Publication Date</u>	<u>Patentee</u>
WO 95/05465	02-23-1995	Amgen Inc.
WO 98/18926	05-07-1998	G.D. Searle & Co.
WO 98/39411	09-11-1998	Baxter International Inc.
WO 98/44141	10-08-1998	The University of British Columbia

WO 99/05268	02-04-1999	Boehringer Mannheim GMBH
WO 00/61164	10-19-2000	Kenneth S. Warren Laboratories
WO 01/38362 A2	05-31-2001	Crucell Holland B.V.
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WO 03/048348 A2	06-12-2003	Crucell Holland B.V.
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WO 2004/003176	01-08-2004	The Kenneth S. Warren Institute, Inc.
WO 2004/099396	11-18-2004	Crucell Holland B.V.
EP 0 411 678	02-06-1991	Genetics Institute, Inc.

Other Documents

BOUT et al., "Improved helper cells for RCA-free production of E1-deleted recombinant adenovirus vectors," *Cancer Gene Therapy*, 1996, pp. S24, Vol. 3, No. 6.

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CARROLL et al., Abstract, *Differential Infection of Receptor-modified Host Cells by Receptor-Specific Influenza Viruses*, *Virus Research*, Sep. 1985, pp. 165-79, Vol. 3, No. 2.

CRONAN, Abstract, *Biotination of Proteins in-vivo a post-translational modification to label purify and study proteins*, *Journal of Biological Chemistry*, June 25, 1990, pp. 10327-33, Vol. 265, No. 18.

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FALLAUX et al, "New helper cells and matched early region 1-deleted adenovirus vectors prevent generation of replication-competent adenoviruses," Human Gene Therapy, Sept. 1, 1998, Vol. 9, No. 1, pp. 1909-1917. Abstract.

GRABENHORST et al., Construction of stable BHK-21 cells coexpressing human secretory glycoproteins and human Gal(beta-1-4)GlcNAc-R alpha-2,6-sialyltransferase alpha-2,6-Linked NeuAc is preferentially attached to the Gal(beta-1-4)GlcNAc(beta-1-2)Man(alpha-1-3)-branch of diantennary oligosaccharides from secreted recombinant beta-trace protein, Eur. J. Biochem, 1995, pp. 718-25, Vol. 232, No. 3, Berlin, Germany.

GRAND et al., "Modulation of the level of expression of cellular genes in adenovirus 12-infected and transformed human cells," Eur Mol Biol Organ J. 1986, 5 (6) 1253-1260. Abstract.

GRAND et al., "The high levels of p53 present in adenovirus early region 1-transformed human cells do not cause up-regulation of MDM2 expression," Virology, 1995, Vol. 210, No. 2, pp. 323-334. Abstract.

HOLLISTER et al., Stable expression of mammalian beta1,4-galactosyltransferase extends the N-glycosylation pathway in insect cells, Glycobiology, 1998, pp. 473-80, Vol. 8, No. 5, IRL Press, United Kingdom.

JENKINS et al., Getting the glycosylation right: Implications for the biotechnology industry, Nature Biotechnology, August 1996, pp. 975-81, Vol. 14, No. 8, Nature Publishing, US.

MINCH et al., Tissue Plasminogen Activator Coexpressed in Chinese Hamster Ovary Cells with alpha(2,6)-Sialyltransferase Contains NeuAc-alpha(2,6)Gal-beta(1,4)Glc-N-AcR Linkages, Biotechnol. Prog., 1995, pp. 348-51, Vol. 11, No. 3.

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SCHIEDNER et al., Abstract, Efficient transformation of primary human amniocytes by E1 functions of Ad5: generation of new cell lines for adenoviral vector production, 2000, Hum. Gene Ther. 11, 2105-2116.

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ZHANG et al., Stable expression of human alpha-2,6-sialyltransferase in Chinese hamster ovary cells: functional consequences for human erythropoietin expression and bioactivity, BBA - General Subjects, 1998, pp. 441-52, Vol. 1425, No. 3, Elsevier Science Publishers, NL.

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, Applicants hereby identify the following listed copending applications naming a common inventor(s):

Attorney Docket No.: 2578-6386US
Serial No.: 10/494,140
Filing Date: 4/29/2004
Title: METHODS AND MEANS FOR PRODUCING PROTEINS WITH
PREDETERMINED POST-TRANSLATIONAL
MODIFICATIONS

Attorney Docket No.: 2578-6471US
Serial No.: 10/499,298
Filing Date: 10/25/2004
Title: EFFICIENT PRODUCTION OF F(AB')2 FRAGMENTS IN MAMMALIAN CELLS

Attorney Docket No.: 2578-6546US
Serial No.: 10/512,589
Filing Date: 10/25/2004
Title: MEANS AND METHODS FOR THE PRODUCTION OF ADENOVIRUS VECTORS

Attorney Docket No.: 2578-3982.3US
Serial No.: 10/783,510
Filing Date: 2/20/2004
Title: MEANS AND METHODS FOR FIBROBLAST-LIKE OR MACROPHAGE-LIKE CELL TRANSDUCTION

Attorney Docket No.: 2578-4038.3US
Serial No.: 10/790,562
Filing Date: 3/1/2004
Title: RECOMBINANT PROTEIN PRODUCTION IN A HUMAN CELL

Attorney Docket No.: 2578-4230.1US
Serial No.: 10/808,681
Filing Date: 3/25/2004
Title: MELANOMA ASSOCIATED PEPTIDE ANALOGUES AND VACCINES AGAINST MELANOMA

Attorney Docket No.: 2578-3833.10US
Serial No.: 10/850,140
Filing Date: 5/20/2004
Title: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO BE USED IN GENE THERAPY

Attorney Docket No.: 2578-4070.2US
Serial No.: 10/951,102
Filing Date: 9/27/2004
Title: SEROTYPES OF ADENOVIRUS AND USES THEREOF

Attorney Docket No.: 2578-4231.1US
Serial No.: 11/018,669
Filing Date: 12/20/2004
Title: GENE DELIVERY VECTORS PROVIDED WITH A TISSUE TROPISM FOR SMOOTH MUSCLE CELLS, AND/OR ENDOTHELIAL CELLS

Attorney Docket No.: 2578-5447.1US
Serial No.: 11/039,767
Filing Date: 1/18/2005
Title: RECOMBINANT PRODUCTION OF MIXTURES OF ANTIBODIES

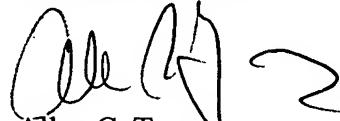
Attorney Docket No.: 2578-6828US
Serial No.: 11/070,890
Filing Date: 3/2/2005
Title: RECOMBINANT PROTEIN PRODUCTION IN PERMANENT AMNIOCYTIC CELLS THAT COMPRISSE NUCLEIC ACID ENCODING ADENOVIRUS E1A AND E1B PROTEINS

Attorney Docket No.: 2578-5006.2US
Serial No.: 11/083,590
Filing Date: 3/18/2005
Title: GENE DELIVERY VECTORS WITH CELL TYPE SPECIFICITY FOR MESENCHYMAL STEM CELLS

Attorney Docket No.: 2578-3955.2US
Serial No.: 11/134,674
Filing Date: 5/19/2005
Title: MEANS AND METHODS FOR NUCLEIC ACID DELIVERY VEHICLE DESIGN AND NUCLEIC ACID TRANSFER

This Information Disclosure Statement is believed to be filed before the mailing date of a first Office Action on the merits; therefore, no fee is due.

Respectfully submitted,



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Date: August 12, 2005
ACT/bv/alb

Enclosures: Form PTO/SB/08
Document in ProLaw



PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

1

of

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Complete if Known

Application Number	10/644,256
Filing Date	August 20, 2003
First Named Inventor	Jones et al.
Group Art Unit	1632
Examiner Name	To be assigned

Attorney Docket Number

2578-6077US

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
		US- 4,703,008	10-27-1987	Lin	
		US- 4,835,260	05-30-1989	Shoemaker	
		US- 5,047,335	09-10-1991	Paulson et al.	
		US- 5,441,868	08-15-1995	Lin	
		US- 5,457,089	10-10-1995	Fibi et al.	
		US- 5,494,790	02-27-1996	Sasaki et al.	
		US- 5,767,078	06-16-1998	Johnson et al.	
		US- 5,773,569	06-30-1998	Wrighton et al.	
		US- 5,789,247	08-04-1998	Ballay et al.	
		US- 5,830,851	11-03-1998	Wrighton et al.	
		US- 5,835,382	11-10-1998	Wilson et al.	
		US- 5,856,298	01-05-1999	Strickland	
		US- 6,033,908	03-01-2000	Bout et al.	
		US- 6,492,169 B1	12-10-2002	Vogels et al.	
		US- 6,558,948	05-06-2003	Kochanek et al.	
		US- 6,855,544	02-15-2005	Hateboer et al.	
		US- 2002/116723 A1	08-22-2002	Grigliatti et al.	
		US- 2003/0087437 A1	05-08-2003	Asada et al.	
		US- 2003/0092160	05-15-2003	Bout et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)			
		WO 95/05465	02-23-1995	Amgen Inc.	
		WO 98/18926	05-07-1998	G.D. Searle & Co.	
		WO 98/39411	09-11-1998	Baxter International Inc.	
		WO 98/44141	10-08-1998	The University of British Columbia	
		WO 99/05268	02-04-1999	Boehringer Mannheim GMBH	
		WO 00/61164	10-19-2000	Kenneth S. Warren Laboratories	
		WO 01/38362 A2	05-31-2001	Crucell Holland B.V.	
		WO 02/053580	07-11-2002	The Kenneth S. Warren Institute, Inc.	
		WO 03/038100 A1	05-08-2003	Crucell Holland B.V.	
		WO 03/048197 A1	06-12-2003	Crucell Holland B.V.	
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		WO 2004/003176	01-08-2004	The Kenneth S. Warren Institute, Inc.	
		WO 2004/099396	11-18-2004	Crucell Holland B.V.	
		EP 0 411 678	02-06-1991	Genetics Institute, Inc.	

Examiner
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

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Sheet

2

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Attorney Docket Number

2578-6077US

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		BOUT et al., "Improved helper cells for RCA-free production of E1-deleted recombinant adenovirus vectors," <i>Cancer Gene Therapy</i> , 1996, pp. S24, Vol. 3, No. 6.	
		BOUT et al., "Production of RCA-free batches of E1-deleted recombinant adenoviral vectors on PER.C6," <i>Nucleic Acids Symp. Ser.</i> 1998, XP-002115716, pp. 35-36.	
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		CARROLL et al., Abstract, <i>Differential Infection of Receptor-modified Host Cells by Receptor-Specific Influenza Viruses</i> , <i>Virus Research</i> , Sep. 1985, pp. 165-79, Vol. 3, No. 2.	
		CRONAN, Abstract, <i>Biotinylation of Proteins in-vivo a post-translational modification to label purify and study proteins</i> , <i>Journal of Biological Chemistry</i> , June 25, 1990, pp. 10327-33, Vol. 265, No. 18.	
		European Search Report 05 10 0732, April 7, 2005.	
		FALLAUX et al., "New helper cells and matched early region 1-deleted adenovirus vectors prevent generation of replication-competent adenoviruses," <i>Human Gene Therapy</i> , Sept. 1, 1998, Vol. 9, No. 1, pp. 1909-1917. Abstract.	
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		GRAND et al., "Modulation of the level of expression of cellular genes in adenovirus 12-infected and transformed human cells," <i>Eur Mol Biol Organ J.</i> 1986, 5 (6) 1253-1260. Abstract.	
		GRAND et al., "The high levels of p53 present in adenovirus early region 1-transformed human cells do not cause up-regulation of MDM2 expression," <i>Virology</i> , 1995, Vol. 210, No. 2, pp. 323-334. Abstract.	
		HOLLISTER et al., Stable expression of mammalian beta1,4-galactosyltransferase extends the N-glycosylation pathway in insect cells, <i>Glycobiology</i> , 1998, pp. 473-80, Vol. 8, No. 5, IRL Press, United Kingdom.	
		JENKINS et al., Getting the glycosylation right: Implications for the biotechnology industry, <i>Nature Biotechnology</i> , August 1996, pp. 975-81, Vol. 14, No. 8, Nature Publishing, US.	
		MINCH et al., Tissue Plasminogen Activator Coexpressed in Chinese Hamster Ovary Cells with alpha(2,6)-Sialyltransferase Contains NeuAc-alpha(2,6)Gal-beta(1,4)Glc-N-AcR Linkages, <i>Biotechnol. Prog.</i> , 1995, pp. 348-51, Vol. 11, No. 3.	

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¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		PACITTI et al., Inhibition of Reovirus Type 3 Binding to Host Cells by Sialylated Glycoproteins Is Mediated through the Viral Attachment Protein, Journal of Virology, May 1987, pp. 1407-15, Vol. 61, No. 5, American Society for Microbiology.	
		PAU et al., Abstract, The human cell line PER.C6 provides a new manufacturing system for the production of influenza vaccines, Vaccine, Mar. 21, 2001, pp. 2716-21, Vol. 19, No. 17-19.	
		PAZUR et al., Abstract, Oligosaccharides as immunodeterminants of erythropoietin for two sets of anti-carbohydrate antibodies, Journal of Protein Chemistry, November 2000, pp. 631-35, Vol. 19, No. 8.	
		SCHIEDNER et al., Abstract, Efficient transformation of primary human amniocytes by E1 functions of Ad5: generation of new cell lines for adenoviral vector production, 2000, Hum. Gene Ther. 11, 2105-2116.	
		STOCKWELL et al., High-throughput screening of small molecules in Miniaturized Mammalian Cell-based Assays involving Post-translational Modifications, Chemistry and Biology, February 1999, pp. 71-83, Vol. 6, No. 2.	
		WEIKERT et al., Engineering Chinese hamster ovary cells to maximize sialic acid content of recombinant glycoproteins, Nature Biotechnology, November 1999, pp. 1116-21, Vol. 17, No. 11, Nature Pub. Co., New York, NY, US.	
		YU et al., "Enhanced c-erbB-2/neu expression in human ovarian cancer cells correlates with more severe malignancy that can be suppressed by E1A," Cancer Res., 1993, 53 (4) 891-8. Abstract.	
		ZHANG et al., Stable expression of human alpha-2,6-sialyltransferase in Chinese hamster ovary cells: functional consequences for human erythropoietin expression and bioactivity, BBA - General Subjects, 1998, pp. 441-52, Vol. 1425, No. 3, Elsevier Science Publishers, NL.	

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